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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,774	12/20/2005	Alexander J Borck	117163.00155	1187
21324 7590 10/16/2008 HAHN LOESER & PARKS, LLP One GOJO Plaza Suite 300 AKRON, OH 44311-1076				
EXAMINER				
CLARK, GREGORY D				
ART UNIT		PAPER NUMBER		
4152				
NOTIFICATION DATE		DELIVERY MODE		
10/16/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com  
akron-docket@hotmail.com

### Office Action Summary

**Application No.**

10/561,774

**Applicant(s)**

BORCK ET AL.

**Examiner**

GREGORY CLARK

**Art Unit**

4152

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 03/21/2008
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### ***Specification Objection***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification is objected to on the basis of a failure to clarify the required sections on the basis of the heading sections shown below. The examiner request that the specification be modified to incorporate the required headings.

### ***Claim Objections***

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. The polysaccharide layer was defined in Claim 1 comprises (a) chitosan and (b) hyaluronic acid or hyaluronic acid derivative. Claim 2 includes chitosan in partial areas or layers of the polysaccharide layer. Since it was already claimed in claim 1 that the layer was partially chitosan and partially a hyaluronic acid, claim 2 does not further limit the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-2, 24 and 25 are rejected under 35 U.S.C. 102(e) as being unpatentable Elliot (2003/0236567).**

***Regarding Claims 1 and 2***, Elliot teaches an implantable prosthesis which may be used as a graft to replace a portion of a bodily passageway (e.g., vascular graft), or may be used within a bodily passageway to maintain patency thereof, such as an endovascular stent-graft (paragraph 20). Elliot teaches that the skirt (outer covering the prosthesis) can be coated with materials that are susceptible to cell ingrowth (tissue simulating) (paragraph 25). These materials include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

***Regarding Claims 24 and 25***, Elliot teaches an implantable prosthesis which may be used as a graft to replace a portion of a bodily passageway (e.g., vascular graft), or may be used within a bodily passageway to maintain patency thereof, such as an endovascular stent-graft (paragraph 20). Elliot teaches that the skirt (outer covering the prosthesis) can be coated with materials that are susceptible to cell ingrowth (tissue

silmulating) (paragraph 25). These materials include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

**Claims 1-3 are rejected under 35 U.S.C. 102(e) as being unpatentable by Wironen (6,685,626).**

***Regarding Claim 1, Wironen teaches a biocompatible (Column 5, lines 43-45) coating (called by the term "a carrier", Column 4, lines 14-20) system for metallic implants (Column 4, lines 30-35). The carrier coating selected from or may be a combination of materials selected from the following non-exclusive list: collagen; gelatin; carboxymethyl cellulose; hyaluronic acid; polyvinyl alcohol; thrombin; fibrin; albumin; and mucoadhesive polysaccharides such as chitosan, polyalcohols, polyamines, polyvinyls, polyamides and polyesters (Column 5, lines 9-17).***

***Regarding Claims 2 and 3, Wironen teaches the usage of a mucoadhesive polysaccharide layer which contains chitosan (Column 5, lines 14 and 15 ).***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wironen (6,685,626).**

**Regarding Claim 4**, Wironen teaches the usage of a mucoadhesive polysaccharide layer which contains chitosan (Column 5, lines 14 and 15). Wironen does not teach the thickness of the chitosan layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the chitosan layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding 5**, Wironen teaches a biocompatible (Column 5, lines 43-45) coating (called by the term "a carrier", Column 4, lines 14-20) system for metallic implants (Column 4, lines 30-35). *The carrier (coating) material is selected from or may be a combination of materials selected from the following non-exclusive list: collagen; gelatin; carboxymethyl cellulose; hyaluronic acid; polyvinyl alcohol; thrombin; fibrin; albumin; and mucoadhesive polysaccharides such as chitosan, polyalcohols, polyamines, polyvinyls, polyamides and polyesters* (Column 5, lines 9-17).

It would have been obvious to one having ordinary skill in the art at the time of

the invention to adjust the weight percent of the chitosan for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding Claims 6 and 7**, Wironen teaches a biocompatible (Column 5, lines 43-45) coating (called by the term "a carrier", Column 4, lines 14-20) system for metallic implants (*Column 4, lines 30-35*). *The carrier (coating) material is selected from or may be a combination of materials selected from the following non-exclusive list: collagen; gelatin; carboxymethyl cellulose; hyaluronic acid; polyvinyl alcohol; thrombin; fibrin; albumin; and mucoadhesive polysaccharides such as chitosan, polyalcohols, polyamines, polyvinyls, polyamides and polyesters* (Column 5, lines 9-17). Wironen does not teach the molecular weight of the hyaluronic acid or hyaluronic acid derivative.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the layer properties by selecting hyaluronic acid with the appropriate molecular weight, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over**



**Elliot (2003/0236567)**

**Regarding Claim 3**, Elliot teaches an implantable prosthesis that can be made from materials that include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

As Elliot uses a like material (chitosan) in a like manner as claimed, it would be expected that the prosthesis (implant) would have the same characteristics claimed, particularly the adhesion properties, absence a showing of unexpected results.

**Regarding Claim 4**, Elliot teaches an implantable prosthesis that can be made from materials that include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the chitosan layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding 5**, Elliot teaches an implantable prosthesis which may be used as a graft to replace a portion of a bodily passageway (e.g., vascular graft), or may be used within a bodily passageway to maintain patency thereof, such as an endovascular stent-graft (paragraph 20). Elliot teaches that the skirt (outer covering the prosthesis) can be coated with materials that are susceptible to cell ingrowth (tissue silmulating)

(paragraph 25). These materials include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the weight percent of the chitosan for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding Claims 6 and 7**, Elliot teaches an implantable prosthesis which may be used as a graft to replace a portion of a bodily passageway (e.g., vascular graft), or may be used within a bodily passageway to maintain patency thereof, such as an endovascular stent-graft (paragraph 20). Elliot teaches that the skirt (outer covering the prosthesis) can be coated with materials that are susceptible to cell ingrowth (tissue simulating) (paragraph 25). These materials include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the layer properties by selecting hyaluronic acid with the appropriate molecular weight, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Claims 8-20 rejected under 35 U.S.C. 103(a) as being unpatentable over**

**Elliot (2003/0236567) in view of Pastorello (6,642, 21311) and Collombel (5,166,187).**

**Regarding Claims 8, 9 and 11**, Elliot does not teach the rate of degradation of the polysaccharide layer (chitosan and hyaluronic acid).

Pastorello teaches that the chemical structure of the hyaluronic acid derivative used and according to the degree of esterification have the advantage of having tensile strength and degradation times that can be adjusted according to the requirement of the area to be reconstructed (Column 3, lines 55-61).

Collombel teaches the usage of chitosan in a biomaterial application where the speed of enzymatic degradation of chitosan is a function both of its molecular weight and its degree of acetylation (Column 5, lines 64-66).

Whereas, Elliot teaches an implantable prosthesis which can be composed of hyaluronic acid and chitosan. Pastorello and Collombel teach that both hyaluronic acid and chitosan can be selected with the appropriate structural features (esterification in hyaluronic acid and acetylation in chitosan) to control the degree of degradation.

The suggestion/motivation for doing so would have been to select the appropriate material with the proper degradation rate (Pastorello, Column 3, lines 55-61).

The suggestion/motivation for doing so would have been to select the appropriate material with the proper degradation rate (Collombel, Column 5, lines 64-66).

It would have been obvious to some of ordinary skill in the art at the time of the invention to combine the biocompatible hyaluronic acid and chitosan implantable prosthesis coating taught by Elliot with the suitable structural features (esterification in hyaluronic acid and acetylation in chitosan) taught by Pastorello and Collombel to give the desired degradation properties in the respective layers.

**Regarding Claim 10**, Elliot, Pastorello, and Collombel teaches the invention of claim 9. Elliot does not teach the thickness of the polysaccharide layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the polysaccharide layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding Claim 12**, Elliot does not teach the thickness of the polysaccharide layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the polysaccharide layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding Claims 13, 14, 16**, Elliot teaches an implantable prosthesis which may be used as a graft to replace a portion of a bodily passageway (e.g., vascular graft), or may be used within a bodily passageway to maintain patency thereof, such as an endovascular stent-graft (paragraph 20). Elliot teaches that the skirt (outer covering the prosthesis) can be coated with materials that are susceptible to cell ingrowth (tissue silmulating) (paragraph 25). These materials include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

Elliot does not mention degradation with respect to polysaccharide layers. Pastorello teaches that the chemical structure of the hyaluronic acid derivative used and according to the degree of esterification have the advantage of having tensile strength and degradation times that can be adjusted according to the requirement of the area to be reconstructed (Column 3, lines 55-61).

Collombel teaches the usage of chitosan in a biomaterial application where the speed of enzymatic degradation of chitosan is a function both of its molecular weight and its degree of acetylation (Column 5, lines 64-66).

Whereas, Elliot teaches a biocompatible coating for implantable prosthesis which can be composed of hyaluronic acid and chitosan. Pastorello and Collombel teach that both hyaluronic acid and chitosan can be selected with the appropriate structural features (esterification in hyaluronic acid and acetylation in chitosan) to control the degree of degradation.

It would have been obvious to some of ordinary skill in the art at the time of the invention to combine the biocompatible hyaluronic acid and chitosan coating

implantable prosthesis coating taught by Elliot with the suitable structural features (esterification in hyaluronic acid and acetylation in chitosan) taught by Pastorello and Collombel to give the desired degradation properties in the respective layers.

**Regarding Claim 15, 17-19**, Elliot, Pastorello and Collombel do not teach the thickness of the polysaccharide layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the polysaccharide layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding Claim 20**, Elliot, Pastorello and Collombel teach the invention of claim 8. Elliot teaches an implantable prosthesis which may be used as a graft to replace a portion of a bodily passageway (e.g., vascular graft), or may be used within a bodily passageway to maintain patency thereof, such as an endovascular stent-graft (paragraph 20). Elliot teaches that the skirt (outer covering the prosthesis) can be coated with materials that are susceptible to cell ingrowth (tissue simulating) (paragraph 25). These materials include: collagen, fibrin, hyaluronic acid, chitosan, and/or other polysaccharide (paragraph 25).

**Claims 8-20 rejected under 35 U.S.C. 103(a) as being unpatentable over**

**Wironen (6,685,626) in view of Pastorello (6,642, 21311) and Collombel (5,166,187).**

**Regarding Claims 8, 9 and 11**, Wironen does not teach the rate of degradation of the polysaccharide layer.

Pastorello teaches that the chemical structure of the hyaluronic acid derivative used and according to the degree of esterification have the advantage of having tensile strength and degradation times that can be adjusted according to the requirement of the area to be reconstructed (Column 3, lines 55-61).

Collombel teaches the usage of chitosan in a biomaterial application where the speed of enzymatic degradation of chitosan is a function both of its molecular weight and its degree of acetylation (Column 5, lines 64-66).

Whereas, Wironen teaches a biocompatible coating for metallic implants which can be composed of hyaluronic acid and chitosan. Pastorello and Collombel teach that both hyaluronic acid and chitosan can be selected with the appropriate structural features (esterification in hyaluronic acid and acetylation in chitosan) to control the degree of degradation.

The suggestion/motivation for doing so would have been to select the appropriate material with the proper degradation rate (Pastorello, Column 3, lines 55-61).

The suggestion/motivation for doing so would have been to select the appropriate material with the proper degradation rate (Collombel, Column 5, lines 64-66).

It would have been obvious to some of ordinary skill in the art at the time of the invention to combine the biocompatible hyaluronic acid and chitosan coating metallic implant coating taught by Wironen with the suitable structural features (esterification in hyaluronic acid and acetylation in chitosan) taught by Pastorello and Collombel to give the desired degradation properties in the respective layers.

***Regarding Claim 10***, Wironen, Pastorello, and Collombel teaches the invention of claim 9. Wironen does not teach the thickness of the polysaccharide layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the polysaccharide layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

***Regarding Claim 12***, Wironen does not teach the thickness of the polysaccharide layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the polysaccharide layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).



**Regarding Claims 13, 14, 16,** Wironen teaches the invention of claim 8.

Wironen teaches a biocompatible (Column 5, lines 43-45) coating (called by the term "a carrier", Column 4, lines 14-20) system for metallic implants (Column 4, lines 30-35).

*The carrier (coating selected from or may be a combination of materials selected from the following non-exclusive list: collagen; gelatin; carboxymethyl cellulose; hyaluronic acid; polyvinyl alcohol; thrombin; fibrin; albumin; and mucoadhesive polysaccharides such as chitosan, polyalcohols, polyamines, polyvinyls, polyamides and polyesters (Column 5, lines 9-17).* Wironen implies that one may select a material from the list shown above or a combination of material which the examiner interrupts to include if desire layers using chitosan or hyaluronic acid or combination thereof. Wironen does not mention degradation with respect to polysaccharide layers.

Pastorello teaches that the chemical structure of the hyaluronic acid derivative used and according to the degree of esterification have the advantage of having tensile strength and degradation times that can be adjusted according to the requirement of the area to be reconstructed (Column 3, lines 55-61).

Collombel teaches the usage of chitosan in a biomaterial application where the speed of enzymatic degradation of chitosan is a function both of its molecular weight and its degree of acetylation (Column 5, lines 64-66).

Whereas, Wironen teaches a biocompatible coating for metallic implants which can be composed of hyaluronic acid and chitosan. Pastorello and Collombel teach that both hyaluronic acid and chitosan can be selected with the appropriate structural features (esterification in hyaluronic acid and acetylation in chitosan) to control the

degree of degradation. It would have been obvious to some of ordinary skill in the art at the time of the invention to combine the biocompatible hyaluronic acid and chitosan coating metallic implant coating taught by Wironen with the suitable structural features (esterification in hyaluronic acid and acetylation in chitosan) taught by Pastorello and Collombel to give the desired degradation properties in the respective layers.

**Regarding Claim 15, 17-19,** Wironen, Pastorello and Collombel *do not* teach the thickness of the polysaccharide layer.

It would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the thickness for the polysaccharide layer for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2<sup>nd</sup> 272, 205 USPQ 215 (CCPA 1980).

**Regarding Claim 20,** Wironen, Pastorello and Collombel teach the invention of claim 8. Wironen teaches a biocompatible (Column 5, lines 43-45) coating (called by the term “a carrier”, Column 4, lines 14-20) system for metallic implants (Column 4, lines 30-35). The carrier coating is selected from or may be a combination of materials which include hyaluronic acid and chitosan (Column 5, lines 9-17).

**Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Elliot (2003/0236567) in view or Swan (5,563,056).**

**Regarding Claim 21**, Elliot teaches the invention of claim 1. Elliot does not teach the polysaccharide layer ( chitosan and hyaluronic acid) is immobilized covalently or through physisorption on the surface of the implant.

Swan teaches a chemical specie can be immobilized in a three dimensional, crosslinked matrix by bringing together in covalent bonding proximity a desired chemical specie and a polymeric coupling compound such as a photoderivatized polymer having at least two latent photochemical reactive groups per molecule, each latent reactive group being capable when activated of covalently bonding to another coupling compound molecule or to the chemical specie (abstract). Swan also teaches such materials which are readily coupled (immobilized) to a surface include oligomers, homopolymers and copolymers resulting from addition or condensation polymerization, and natural polymers including nucleic acids, oligosaccharides, linear polysaccharides such as amylose, dextran, chitosan, heparin and hyaluronic acid, and branched polysaccharides such as amylopectin, glycogen and hemi-celluloses (Column 3, lines 54-63). Swan also teaches that the immobilization of chemical species (on the surfaces of prostheses that are to be implanted within the body) with growth factors or similar chemical species may contribute to the rapid proliferation of tissue (biocompatibility/ tissue growth) on the prosthesis (Column 1, lines 21-25).

Whereas both chitosan and hyaluronic acid homopolymers and copolymers can be immobilized on a surface covalently it would have been obvious to someone of

ordinary skill in the art at the time of the invention to combine to biocompatible metallic implant coatings taught by Elliot with the immobilization technique taught by Swan.

**Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wironen (6,685,626) in view of Swan (5,563,056).**

**Regarding Claim 21**, Wironen teaches the invention of claim 1. Wironen does not teach the polysaccharide layer is immobilized covalently or through physisorption on the surface of the implant.

Swan teaches a chemical specie can be immobilized in a three dimensional, crosslinked matrix by bringing together in covalent bonding proximity a desired chemical specie and a polymeric coupling compound such as a photoderivatized polymer having at least two latent photochemical reactive groups per molecule, each latent reactive group being capable when activated of covalently bonding to another coupling compound molecule or to the chemical specie (abstract). Swan also teaches such materials which are readily coupled (immobilized) to a surface include oligomers, homopolymers and copolymers resulting from addition or condensation polymerization, and natural polymers including nucleic acids, oligosaccharides, linear polysaccharides such as amylose, dextran, chitosan, heparin and hyaluronic acid, and branched polysaccharides such as amylopectin, glycogen and hemi-celluloses (Column 3, lines 54-63). Swan also teaches that the immobilization of chemical species (on the surfaces of prostheses that are to be implanted within the body) with growth factors or similar

chemical species may contribute to the rapid proliferation of tissue (biocompatibility/tissue growth) on the prosthesis (Column 1, lines 21-25).

Whereas both chitosan and hyaluronic acid homopolymers and copolymers can be immobilized on a surface covalently it would have been obvious to someone of ordinary skill in the art at the time of the invention to combine to biocompatible metallic implant coatings taught by Wironen with the immobilization technique taught by Swan.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY CLARK whose telephone number is (571)270-7087. The examiner can normally be reached on M-Th 7:00 AM to 5 PM Alternating Fri 7:30 AM to 4 PM and Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GDC

/Joseph S. Del Sole/  
Supervisory Patent Examiner, Art Unit 4152